DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 28 July 2008.

Status of Previous Action

The applicant has requested reconsideration of the Finality of the Office Action (filed 7/28/2008). Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Status

Claim 10 is amended. Claims 4-9 and 11-38 are cancelled. Claims 1-3, 10 and 39 are under current examination.

Priority

This application claims benefit from PCT/US02/08288 (filed 14 March 2002) which claims benefit from provisional US Application 60/314,046 (filed 22 Aug 2001) and from provisional US Application 60/322,993 (filed 18 Sept 2001). The instant application has been granted the benefit date, 22 August 2001, from the application 60/314,046.

Response to Arguments - Claim Rejections 35 USC § 102

The rejection of claims 4-5 as anticipated over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997), is withdrawn in response to Applicant's amendment or arguments.

The applicant's amendments cancelling claim 4 and 5 have overcome the rejection of claims 4-5 as anticipated by Lamerdin et al.

Accordingly, the rejection of claims 1-2 as anticipated by Lamerdin et al. is hereby withdrawn.

Response to Arguments - Claim Rejections 35 USC § 103

The rejection of claims 4-6 as unpatentable over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997), is withdrawn in response to Applicant's amendment or arguments.

The applicant's amendments cancelling claim 4-6 have overcome the rejection of claims 4-6 as unpatentable over Lamerdin et al.

Accordingly, the rejection of claims 4-6 as unpatentable over Lamerdin et al. is hereby withdrawn.

The rejection of claims 10-12 as unpatentable over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997) in view of Liu et al. (Current Biology, 19 November 1998; 8:1300-1309), is withdrawn in response to Applicant's amendment or arguments.

The applicant's amendments cancelling claim 11-12 and portions of claim 10 have overcome the rejection of claims 10-12 as unpatentable over Lamerdin et al. in view of Liu et al.

Accordingly, the rejection of claims 4-6 as unpatentable over Lamerdin et al. in view of Liu et al. is hereby withdrawn.

NEW GROUNDS OF REJECTION

Claim Objections

Claims 1 and 39 are objected to because of the following informalities: The syntax of claims 1 and 39 are not completely clear. The examiner recommends the following changes to improve the clarity of the claims:

In claim 1, the words "full-length" should be added in line 4 between the word "the" and the word "complement."

In claim 39, the words "the polypeptide" should be added before the words "SEQ ID NO:2" in line 2. In addition, the words "nucleic acid sequence encodes a" should be deleted from lines 2-3. Also, the word "that" should be deleted from before the word "reduces" in line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is directed to the isolated nucleic acid molecule according to Claim 1, which is RNA. This is confusing, since Claim 1 is directed to DNA. RNA cannot be DNA. Therefore, the examiner recommends deleting claim 3 and replacing it with a claim such as by "An isolated RNA that encodes SEQ ID NO:2." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 10 are rejected under 35 U.S.C. 103(a) as being obvious over Linsley et al (US2003/0119024).

Linsley et al (US2003/0119024) which has provisional support to July 20, 2001 (Provisional US Application 60/306,968), about one month before the priority date of the instant application. Linsley et al. teach a polypeptide, SEQ ID NO:11 (465 amino acids), which shares 94.6% identity to SEQ ID NO:2 of the instant application and SEQ ID NO: 13 (313 amino acids) which shares 94.2% identity to SEQ ID NO:2 of the instant application; Linsley et al. refer to these polypeptides as the long form and short form of TA-NFKBH, respectively. The Linsley SEQ ID NO:11 and instant SEQ ID NO:2 share 100% identity for 312 contiguous amino acids of the 328 amino acids of SEQ ID NO:2. Linsley et al. teach that that both their long and short forms of TA-NFKBH (465 aa and 313aa, respectively) contain 5 ankyrin repeats, particularly between amino acids 84-279 of the short form (see Figure 11 of Linsley). Linsley et al. teach Figure 6, cDNA sequence (SEQ ID NO:10) that encodes the long form of TA-NFKBH (SEQ ID NO:11) (parag.0051). Linsley et al. teach Figure 7, cDNA sequence (SEQ ID NO:12) that encodes the short form of TA-NFKBH (SEQ ID NO:13) (parag.0052).

The instant specification indicates that IkBNS contains seven ankyrin repeats (page 2, line 12). The instant application also indicates that the cDNA for IkBNS

encodes a 327 amino acid protein containing 7 ankyrin domains (labeled A-G, Figure 2) (page 47, lines 24-28). According to an alignment of the Linsley et al. peptide sequences and the polypeptide sequences coding for IkBNS, the Linsley et al. polypeptides contain all seven ankyrin domains. Importantly, it seems that the instant specification seems to be emphasizing the novelty of ankyrin domain D of IkBNS, whose structure is different from other members of the IkB family. While not emphasizing the importance of this domain, Linsley et al. teach this sequence as part of their polypeptide TA-NFKBH, described above.

While, the instant claims define their sequence as "consisting" of SEQ ID NO:1, the specification does not describe the importance of the N-terminus which differs from the important 312 amino acids having 100% identity to the sequences of Linsley et al., which have encompass all 7 ankyrin domains of IkBNS (and TA-NFKBH) .

According to MPEP 2143, Ex Parte Kubin (83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007) suggests a skilled artisan would have been able to use employ conventional methods to determine the nucleic acid sequence, provided disclosure of a polypeptide sequence. In the instant case, the important functional domains of the claimed IkBNS polypeptide were disclosed by Linsley et al. as TA-NFKBH.

An artisan would have expected success, because the techniques were known in the art.

Therefore the isolated nucleic acids and vectors as taught by Linsley et al would have been *prima facie* obvious over the isolated nucleic acids and vectors of the instant application.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linsley et al (US2003/0119024) as applied to claim 1 above, and further in view of Allcock et al. (Immunogenetics. January 2001 (online); 52: 289-293).

Claim 39 is directed to an isolated nucleic acid molecule consisting of a nucleic acid sequence that encodes SEQ ID NO:2, wherein said nucleic acid sequence encodes a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells.

The teachings of Linsley et al. are described above in the previous 35 USC 103 rejection.

Linsley et al. do not teach testing their sequences for NF-kB sensitive reporter activity in Cos cells.

However, Allcock et al. teach testing nucleic acids encoding an Inhibitory-kappa-B-like (IkBL) protein for NF-kB binding activity in COS cells (page 293, col.1). Clearly, Allcock et al. teach the concept of testing the activity of nucleic acids which encode NF-kB inhibitory molecules which are part of the IkB family by testing NF-kB binding activity in COS cells.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to test a molecule sharing identity to members of the IkB family for NF-kB inhibitory activity in COS cells.

The person of ordinary skill in the art would have been motivated to test using these cells and methods because it was standard practice in the art, as suggested by Allcock et al.

Absent evidence to the contrary, an artisan would have expected success, because there is nothing unusual about testing a sequence in cell culture.

Therefore the isolated nucleic acids as taught by Linsley et al in view of Allcock et al. would have been *prima facie* obvious over the isolated nucleic acids of the instant application.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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